UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR RECONSIDERATION OF THE COURT'S DECEMBER 13, 2017 ORDER ON GENERAL CAUSATION

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INTRODUCTION

On reconsideration of its December 13, 2017 order on general causation, the Court should exclude the opinions of Plaintiffs' medical experts, exclude the model of Plaintiffs' computational fluid dynamics (CFD) expert, and grant summary judgment in favor of Defendants. The Court's subsequent rulings, the trial testimony of Plaintiffs' experts in *Gareis*, and newly published scientific evidence remove any basis to admit Plaintiffs' medical experts' opinions.

The general causation opinions of Plaintiffs' medical experts (Drs. Samet, Jarvis, and Stonnington) depend on the 2011 McGovern study (called the "Observational Study" in the Court's order), the sole epidemiological study they cite that associates an increased risk of periprosthetic joint infections (PJIs) with use of the Bair Hugger system. Because the Observational Study expressly does not establish a causal relationship between the Bair Hugger system and PJIs,[1] Plaintiffs' experts infer general causation based on two causative mechanisms. First, they advance the "airflow disruption theory," whereby the Bair Hugger system disrupts the protective "forcefield" around the patients and causes contaminated skin cells to enter the surgical wound. Second, they propose a theory whereby the Bair Hugger system harbors bacteria and emits them at the patient through the blanket. *See Gareis*, No. 16-4187, Dkt. No. 306, Order at 1 (describing the two theories).

[1] DX1, McGovern at 1543 ("This study does not establish a causal basis for this association.").

Plaintiffs' Second Theory of Causation Is Inadmissible. In *Gareis*, the Court excluded Plaintiffs' theory that the Bair Hugger emits bacteria during surgeries, finding that Plaintiffs lacked any scientific evidence to support it. *Gareis*, Dkt. No. 306, Order at 3. The Court's ruling did not depend on case-specific facts in *Gareis*. The Court noted that none of Plaintiffs' experts' reports cites any evidence of any pathogen "coming out of the 'business end' of the Bair Hugger – the perforated blanket." *Id.* Thus, Plaintiffs are now limited to their airflow disruption theory of general causation.

Elghobashi's Trial Testimony Confirmed that His CFD Cannot Support Plaintiffs' Airflow Disruption Theory. Plaintiffs' medical experts relied on Elghobashi's CFD to support their airflow disruption theory, claiming that the Bair Hugger system disrupts the "forcefield" that protects patients on the operating table. But at the *Gareis* trial, Elghobashi ridiculed the "forcefield" concept as "absolute rubbish" and "silly," and said those who advance the idea "don't know turbulence." DX13, *Gareis* Trial Tr. at 974:4-15. Elghobashi admitted that his own CFD depicts (in his phrase) a "pure operating room" that does not account for many of the sources of turbulence that would be found in any real-world OR. These include movement of medical personnel, opening and closing of doors, and equipment that generates heat or blows air. As Elghobashi explained, his CFD shows that the Bair Hugger system could disrupt airflow in that idealized, "pure" OR. The CFD does not show, however, whether the Bair Hugger system has a meaningful impact on airflow in a *real* OR, where there are many other sources of turbulence. And contrary to Plaintiffs' representations, the CFD also never shows any particle entering the surgical wound – and Elghobashi never claimed that it does. General causation requires more than

just demonstrating a theoretical possibility of causation in some idealized world. To "fit" the facts of the cases in the MDL, it requires demonstrating that the Bair Hugger system causes PJIs in *real* surgeries like the ones in this MDL. *See, e.g.*, *In re Gen. Mots. LLC Ignition Switch Litig.*, 15-CV-1626, 2017 WL 6729295, *7-8 (S.D.N.Y. Dec. 28, 2017) (proof of general causation requires proof of real world occurrence). Elghobashi's CFD does not do that. It does not support Plaintiffs' medical experts' inference of causation, it does not help the jury, and it should be excluded.

Dr. Reed's New Study Demonstrates that the Observational Study Is Unreliable. Last July, Dr. Mike Reed (senior author of the Observational Study) and his colleagues published a study addressing the impact of screening patients for methicillin-sensitive *Staphylococcus aureus* (MSSA) before surgery. The study includes the patients and time period from the Observational Study. The study demonstrates that MSSA screening and decolonization reduced *staph aureus* infections by two-thirds, and the overall infection rate also went down by a statistically significant amount. Considered together with the many other acknowledged confounders, the Observational Study can no longer serve as a reliable basis for Plaintiffs' medical experts to make an inference of general causation.

Plaintiffs' experts' lack of a reliable foundation for inferring general causation is further underscored by the new consensus statements of the International Consensus Meeting on Musculoskeletal Infection (ICM). ICM delegates recently voted by a margin of 93 percent to 2 percent to endorse the statement that "[t]here is no evidence to definitely link FAW [forced air warming] to an increased risk of SSIs/PJIS [surgical site infections/periprosthetic joint infections]." In a statement of rationale, the ICM specifically

addressed the Observational Study, Elghobashi's CFD, and other studies cited by Plaintiffs' experts, and concluded that there is a "lack of strong evidence linking FAW to increased risk of SSI." DX2, 2018 ICM at 113. The three listed authors of the ICM rationale include Dr. Reed.

These developments present compelling circumstances for the Court to revisit its December 2017 Order. L.R. 7.1(j). Without their airflow theory of causation, the CFD, and the Observational Study, Plaintiffs' medical experts lack scientific support to make the inferential leap to general causation. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Accordingly, their opinions are fundamentally unsupported and should be excluded. *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004). Elghobashi's CFD and opinion should also be excluded, because they do not fit the facts of the real-world cases in this MDL, do not support Plaintiffs' theory of causation, and therefore are no help to the jury. *See Group Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 761 (8th Cir. 2003) (affirming exclusion of expert based on "disconnect between [expert's] work and the [plaintiffs'] theory of liability"). Summary judgment should follow. *See, e.g.*, *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 944-45, 968 (D. Minn. 2009) (granting summary judgment following exclusion of plaintiffs' general causation expert).

If the Court denies this motion, Defendants respectfully request that the Court certify the general causation issue under 28 U.S.C. § 1292(b). It is already at issue in the pending *Gareis* appeal, where Defendants will raise the inadmissibility of Plaintiffs' experts' testimony as an alternative basis to affirm the judgment.

ARGUMENT

When the Court analyzes admissibility of expert testimony under Fed. R. Evid. 702, the "overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594-95 (1993). The party calling an expert must demonstrate the reliability of the expert's opinion by a preponderance of the evidence. *Id.* at 592 n.10; *Khoury v. Philips Med. Sys.*, 614 F.3d 888, 892 (8th Cir. 2010).

An expert offering a general causation opinion must reliably "rule in" the defendant's product as a plausible cause of the plaintiffs' injuries. *See Viagra*, 658 F. Supp. 2d at 959-60. "[W]here [an expert's] factual basis, data, principles, methods, or their application are called sufficiently into question . . . the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of the relevant discipline.'" *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) (*quoting Daubert*, 509 U.S. at 592). "Expert testimony developed solely for litigation can weigh against reliability." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2017). Moreover, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. And of course, the district court may exclude expert opinions that are not "sufficiently tied to the facts of the case." *Daubert*, 509 U.S. at 591.

District courts enjoy "broad discretion" in determining whether expert testimony is admissible. *In re Prempro Prods. Liab. Litig.*, 514 F.3d 825, 833 (8th Cir. 2008). District courts' gatekeeping function under *Daubert* and the Federal Rules of Evidence "is a

continuing obligation and requires the court to strike expert testimony that does not meet *Daubert* standards." *NetQuote, Inc. v. Byrd*, No. 07-cv-00630-DME-MEH, 2008 WL 457528, *1 (D. Colo. Oct. 14, 2008) (collecting cases). A court may reverse its earlier decision to admit expert testimony after hearing the expert's testimony at trial. *See, e.g.*, *id.* (reversing earlier decision to admit expert's causation opinion, after hearing the expert's testimony at trial); *Mems v. City of St. Paul – Dep't of Fire & Safety Servs.*, No. CIV. NO. 97-1589 (PAM), 2002 WL 334411, *2 (D. Minn. Feb. 20, 2002) (explaining on new trial motion that it was not error for court to reconsider and reverse its earlier *Daubert* ruling after hearing trial testimony); *cf. Luce v. U.S.*, 469 U.S. 38, 41-42 (1984) (noting that "even if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous *in limine* ruling"). The court may also reverse its earlier *Daubert* decision based on newly available evidence concerning the reliability of the data relied upon by an expert. *See Viagra*, 658 F. Supp. 2d at 942-45, 950 (after initially denying *Daubert* motion to exclude plaintiff's medical expert, MDL court considered new evidence of problems with key epidemiological study and excluded expert).

As discussed below, the trial testimony of Dr. Elghobashi in *Gareis* and the new study co-authored by Dr. Reed on MSSA screening make it impossible for Plaintiffs to carry their burden to demonstrate the admissibility of their experts' testimony. The analytical gap between Elghobashi's CFD and Observational Study, on the one hand, and Plaintiffs' experts' general causation opinions, on the other, is simply too great.

I. BY THE COURT'S ORDER IN *GAREIS*, PLAINTIFFS HAVE BEEN LIMITED TO THEIR AIRFLOW DISRUPTION THEORY.

As an initial matter, the general causation issue has been narrowed since the Court's December 2017 order on general causation.

At the general causation hearing, Plaintiffs advanced two theories of general causation. The Court has described these as follows: "One is that the operation of the Bair Hugger disrupts operating room airflow and causes ambient bacteria to be deposited into the surgical site or onto the prosthetic joint. . . . A second theory of causation is that the Bair Hugger itself harbors bacteria, and that these bacteria escape the warming unit during surgery." *Gareis*, No. 16-4187, Dkt. No. 306, Order at 1.

In *Gareis*, the Court barred Plaintiffs from pursuing the second theory of causation. The Court concluded that Plaintiffs had failed to offer sufficient proof to support that theory at trial: "[N]o expert brought to the Court's attention has tested the air coming out of a Bair Hugger's blanket and discovered escaping colony-forming units. The test would be feasible; it is certainly not cutting edge." *Id.* at 3. Plaintiffs' experts "have examined Bair Huggers in operation. They have not, however, shown any pathogen coming out of the 'business end' of the Bair Hugger, the perforated blanket." *Id.* While the Court made this evidentiary ruling in *Gareis*, its logic carries across the MDL because the Court's analysis was not limited to and did not depend upon the case-specific facts in *Gareis*.

Because general causation is now narrowed to Plaintiffs' first theory, that the Bair Hugger system "disrupts operating room airflow and causes ambient bacteria to be deposited into the surgical site or onto the prosthetic joint," the Court may now focus on

the airflow disruption theory as Plaintiffs' medical experts' only basis for attributing the association found in the Observational Study to the Bair Hugger system.

II. DR. ELGHOBASHI'S TRIAL TESTIMONY VITIATED PLAINTIFFS' AIRFLOW DISRUPTION THEORY OF CAUSATION.

A. According to Plaintiffs' Medical Experts, the Bair Hugger System Introduces Turbulent Airflow into the "Forcefield" Around the Patient.

At the *Gareis* trial, Plaintiffs and their medical experts articulated the airflow disruption theory as follows. They argued that steady "unidirectional" flow of filtered air from the HVAC system creates a protective "forcefield" (which they also sometimes referred to as a "sterile field"[2] or "laminar" airflow) around the patient on the operating table. They further argued that the warm air introduced by the Bair Hugger system creates turbulence and disrupts that "forcefield." The introduction of turbulence, they claim, allows particles to be swept by air currents toward the patient and into the open wound. They further claim that some of these particles are contaminated with bacteria, and that those bacteria seed the wound and develop into a PJI.

In their opening statement, Plaintiffs introduced the idea of the "forcefield" created by unidirectional airflow in the operating room:

> And what happens with that HVAC system, air comes in from the ceiling, and it creates a kind of force field. It pushes down any kind of particles that carry germs and bacteria to the floor, and then there are vents that take those germs or bacteria, particles out of the room. ***It's a kind of force field intended to protect the patient***.

[2] Trial Tr. at 368:12-17 (Stonnington) ("Q. You talked about force field -- sort of a force field. I think that's also known as a sterile field. Is that right? A. Yes, sir. Q. That's kind of the professional term for it? A. Yes, sir.").

> And at some point, some of that hot air [from the Bair Hugger blanket] escapes the bottom edge of the drape. And what happened when hot air escapes the bottom edge of the drape? It rises because heat rises.
>
> And what happens then? ***It interferes with the force field that's intended to protect the patient. That's what happens. That's what the evidence will show in this trial***.

Trial Tr. at 6:6-11, 7:4-10 (emphasis added). Plaintiffs' first expert witness was Dr. Stonnington, an orthopedic surgeon, not an expert in "forcefields" or operating room airflow. Stonnington likewise invoked the protective "forcefield" created by the unidirectional flow of air:

> Q. . . .Describe to me what unidirectional flow is and how it protects the patient from infection risks.
>
> A. This is what I'm talking about. When we walk into a room, we bring a bunch of our stuff with us. What I tell my team every day and they say, Yeah, Doc, we know, bacteria is your number one enemy. Well, it is. It's my number one enemy because it's my patient's number one enemy. The way we do it is create a unidirectional -- protect the patient is create a force field is that you can see -- can I draw on this?
>
> Q. Yep.
>
> A. This is -- up here are the diffusion panels where air is being -- clean air is being pushed through into the operating room. And it pushes those falling skin cells, and lint, and dust, and everything that we don't like on our patients down and out, so away. ***It's basically creating this force field that the patient is in, and all that stuff is being exhausted to the returns or the exhaust fans in the room.*** So clean air coming down. How we get that clean air? We do it through filtered air. We have a filter that is often a HEPA filter and close to one hundred percent filtration -- never one hundred percent because we're humans; I think it's 99.97 percent filtering out at a certain size of particle.

Trial Tr. at 366:2 to 367:1 (emphasis added).

Plaintiffs then called Dr. Jarvis, an infectious disease expert and also not an expert in operating room airflow. Jarvis again invoked the protective "forcefield" purportedly disrupted by the Bair Hugger system:

> A. . . . We control the skin cells on the skin through our prep and we try our best to control the skin cells ***through this unidirectional air through this force field*** which takes those cells, those particulates, that dust and pushes it out through the return vents and protects the patient, and so that's what I meant. Those skin cells carry bacteria. A significant percentage of them carry bacteria.
>
> Q. The prosthesis, can you hold that up? How does a bacteria get from wherever it is on a skin cell onto that prosthesis during a surgery?
>
> A. If you didn't have that force field protection from the unidirectional air, the skin cells can actually come up from the floor in the air and do that (witness indicates.)
>
> Q. Is that called airborne contamination?
>
> A. That's airborne contamination, and that is through decades of research, that is the source of intraoperative infections.

Trial Tr. at 512:12-513:4.[3]

Collectively, Plaintiffs' medical experts rely on two sources for their theory that the Bair Hugger system disrupts the protective "forcefield" and delivers contaminated particles into the surgical wound. Samet and Jarvis rely on Elghobashi's CFD.[4] Dkt. No. 935, SJ

[3] Dr. Samet, also not an expert in operating room airflow, did not testify at the *Gareis* trial. But he also articulated the theory in his general causation expert report: "[D]isruption of protective unidirectional flow across the surgical field and an increased load of microorganisms in the air due to . . . turbulence-driven flow distributing contaminated skin flakes (squames) into the operative field." Dkt. No. 751-1, Samet Rpt. at 13.

[4] Dr. Stonnington did not expressly rely on Elghobashi's CFD in his general causation report or at the *Gareis* trial.

Opp. at 10; *see also* Dkt. No. 751-1, Samet Rpt. at 14-15, Jarvis Rpt. at 14. Samet, Jarvis, and Stonnington collectively cite six articles that purportedly provide further support for their contention that the Bair Hugger transports particles to the surgical site: McGovern 2011, Dasari 2012, Belani 2013, and Legg (2012 and 2013). Dkt. No. 751-1, Samet Rpt. at 15, Jarvis Rpt. at 10-11, Stonnington Rpt. at 6. None of these sources, in fact, supports Plaintiffs' forcefield disruption theory. Defendants address each in turn.

B. Elghobashi Repudiated Plaintiffs' Foundational Premise of the Sterile "Forcefield" and Laminar Airflow in the Operating Room.

At the general causation hearing and at trial, Plaintiffs offered Dr. Elghobashi as their expert on airflow and turbulence. Based on his qualifications and experience, as well as his work in developing his CFD, Elghobashi repeatedly and forcefully repudiated Plaintiffs' foundational premise: the idea of a protective "laminar" forcefield created by unidirectional airflow in the operating room. This idea was (in his words), "absolute nonsense" and "rubbish":

> "By the way, in any hospital room, in any hospital room people misuse the word laminar. There is no laminar flow in any operating room. Never. If you want to change the air in an operating room 25 times per hour, the flow is turbulent, period."
>
> Q. All right. And in any event, the airflow in an operating room is turbulent; is that right?
>
> A. Always, always, but the many publication[s] that says [sic] laminar flow, there is no laminar flow in the room, yeah. The flow in this room also is turbulent."
>
> "[T]here is no laminar flow in an operating room."
>
> "Q. So anybody claiming there's laminar flow and it creates [a] force field?

> A. Right.
>
> Q. It's not just rubbish, it's absolute rubbish?
>
> A. Absolute rubbish, and I give an excuse because that person does not know turbulence.
>
> Q. They don't know turbulence and they don't know what they're talking about?
>
> A. No, because they don't know turbulence, they make silly statement."

Trial Tr. at 846:21-25, 847:16-20, 973:18-19, 974:4-14. Elghobashi further rejected Plaintiffs' contention that the hospital HVAC system creates "unidirectional" airflow downwards around the patient: "And in the operating room, some people call it unidirection just absolute nonsense. You've seen the videos, it's all eddies everywhere. There is nothing called unidirectional when you have a grille [that is, a vent cover through which air is blow into a room] pushing air or anything into a room, nothing."[5] Tr. at 978:15-19.

Dr. Elghobashi's testimony devastated Plaintiffs' airflow disruption theory of general causation. As he made very clear, the foundational premise – the "forcefield" created by the OR's unidirectional airflow – was false. It does not prove what Plaintiffs' medical experts relied upon it to prove. *See Shuck v. CNH Am., LLC*, 498 F.3d 868, 875 n.3 (8th Cir. 2007) (concluding that "testing, if performed, must be appropriate in the circumstances and must actually prove what the experts claim it proves" (discussing

[5] In his expert report, Elghobashi explains that the medical literature "uses the terminology 'laminar flow' for the ultra-clean ventilation flow" – that is, as a synonym for filtered unidirectional air. DX3, Elghobashi Rpt. at 5 n.1. In his trial testimony, he rejected the concept as "rubbish," regardless of the terminology used.

Fireman's Fund Ins. Co. v. Canon U.S.A., Inc., 394 F.3d 1054 (8th Cir. 2005)); *Mems*, 2002 WL 334411, *2.

C. Elghobashi Confirmed that His CFD Does Not Show the Impact of the Bair Hugger System on Airflow in a Realistic Operating Room.

Dr. Elghobashi went on to explain that his CFD model did not reflect many of the sources of turbulence and particles that one would expect in an operating room. While the CFD included surgical lamps and tables, it did not include computers, electrocautery devices, surgical saws, or other sources of heat and air movement in the OR. Elghobashi agreed that airflow in a real operating room would be more turbulent if these types of sources were factored in: Trial Tr. at 976:12-16 ("I could have added more things that would have enhanced the spreading of squames, absolutely. Any additional heating from a fan, from a machine will create its own plume that will resist the cooler air coming from the ceiling so it will be much worse."); *id*. at 952:3-4 ("[I]n addition, any electric device that generates heat with a fan will create its own plume."). Opening and closing of doors – which does not occur in his CFD – would increase turbulence. *Id.* at 961:25-962:1 ("If you open the door or let the people move, you will enhance the spreading of squames."). He also concurred that in a real OR the medical personnel move, unlike the stationary figures in his CFD. *Id.* at 961:7-9. And in his expert report, Elghobashi further notes that "other medical equipment within the operating room (surgical lights, tables, patient, computers, etc.), motion of surgeon's arms and their bending motion can disrupt this air flow and create

wakes, flow unsteadiness, and turbulence, thereby increasing the amount of cfu in the OR." DX3, Elghobashi Rpt. at 1-2 (internal citation omitted).[6]

So why did Dr. Elghobashi not replicate the conditions of an actual operating room, including the movement of personnel, opening and closing of doors, and other medical equipment that generate heat and turbulence? For one thing, it is too difficult to capture these real-world factors in a computer simulation, as he notes in his report and as Plaintiffs conceded in their closing argument. DX3, Elghobashi Rpt. at 4 (stating that using a CFD to model an OR "is a difficult task due to the size and complexity of the domain involving medical equipment, staff, computers, etc."); Trial Tr. at 2152:23 to 2153:1 (MR. FARRAR: "You can't replicate people moving. People would move differently every time. There's no doors opening and closing. You can't replicate doors opening and closing every time."). But the primary answer lies in the premise he was testing. At trial, Elghobashi insisted that his CFD was the "best case" for 3M. Trial Tr. at 881:8-13, 890:1-12. What he meant by this paradoxical phrasing was that he was testing conditions as close as reasonably possible to the "forcefield" ideal (in his phrasing, he "wanted to have a pure operating room"). *Id.* at 952:6-8. He was trying to determine, when one eliminates many of the known sources of turbulence and particulates in the OR, whether the Bair Hugger system can *by itself* affect particulates near the surgical site. *Id.* at 890:1-12.

[6] He also eliminated other known sources of "squames" (shed skin cells). For example, "we put the squames only on the floor, not anywhere in the room." Trial Tr. at 881:8-13. Even though five people (a standard number of individuals in the OR) could shed a hundred million squames per hour, he put only 3 million squames in the room in his CFD, and only on the floor. *Id.* at 881:14-20.

Elghobashi was not, however, trying to determine whether the Bair Hugger system would cause PJIs in a realistic OR with many other sources of turbulence and particulates. Indeed, near the conclusion of his report, he "emphasized that if we also include the repetitive motion of the surgeons, the motion of medical assistants to fetch the surgical instruments placed on the side tables, and the resulting suspended squames shed by all staff in the OR, then the probability of dispersing the squames to the surgical site will be increased even further." DX3, Elghobashi Rpt. at 62. Nowhere does Elghobashi's CFD or testimony address the movement of squames with the Bair Hugger system turned off[7] and all these real-world factors at play. In every case in this MDL, Plaintiffs will ultimately have to prove that their PJIs would not have occurred but for the use of the Bair Hugger system, or that the Bair Hugger system was a substantial contributing cause. Elghobashi's CFD does not and cannot answer this question in any of the cases.

These important points were all either missed or ignored by Plaintiffs and their medical experts as they advanced their "forcefield" fiction. Elghobashi's CFD was a "pure" representation of an ideal operating room that bears no resemblance to reality. Indeed, Elghobashi took pains in his trial testimony to make everyone understand that airflow in a

[7] In trying to "isolate" the Bair Hugger system, Elghobashi's CFD misleadingly implies that the Bair Hugger system is the only variable in an operating room, and that squames could not reach the surgical site without the Bair Hugger system operating. The Court raised this concern at the *Daubert* hearing in *Gareis*. DX14, 4/12/18 Tr. at 50:22-57:7 (posing the question of "prejudice of [Elghobashi] talking about what would happen in Gareis's operating room if the Bair Hugger had not been in the on position").

real operating room would always be turbulent and that additional turbulence – and risk of spreading squames – would be introduced by the personnel and machinery in the room.

In short, Plaintiffs' medical experts' causal inference – that the Bair Hugger causes PJIs because it disrupts the "forcefield" in real surgeries in real ORs – is flatly contradicted by Elghobashi's trial testimony. Moreover, Plaintiffs' medical experts lack a scientific basis (and, in any event, they are not qualified to offer any), to extrapolate from Elghobashi's unrealistic, idealized OR, to what occurs in a real OR with many other sources of air movement. *See, e.g.*, *Mirena IUD*, 169 F. Supp. 3d at 441-42 (excluding general causation expert's opinion, which was based on a lab test using "equipment apparently intended to mimic the uterus": "Dr. Jarrell's constrained testing conditions do not reliably replicate the conditions inside a woman's uterus, and therefore render his methodology and the conclusions he draws from it unreliable"); *Winebarger v. Boston Sci. Corp.*, No. 13-CV-28892, 2015 WL 1887222, *17 (S.D. W.Va. Apr. 24, 2015) (testing that produced results at very high temperatures that could not be replicated in human body did not fit facts of case and was therefore irrelevant and unhelpful); *Bland v. Verizon Wireless (VAW) L.L.C.*, No. 3:06-CV-00008-CFB, 2007 WL 5681791, *9 (S.D. Iowa Aug. 9, 2007) (excluding medical causation expert who lacked a reliable basis to "extrapolate from a theoretical toxic risk to a real world conclusion about causation" (internal quotation omitted)), *aff'd*, 538 F.3d 893 (8th Cir. 2008); *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1303 (M.D. Fla. 2007) ("This Court's gate-keeping function is to ensure that opinions based on mere theory do not reach the jury . . . [An expert's] opinion may very

well be correct. His conclusions may be proven true. But at this point there is a gap between the data and the opinions he proffers.").

Their airflow disruption theory should therefore be excluded. At the *Gareis* trial, it proved to be no more than "scientific guesswork," which has no place in the courtroom. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags behind science; it does not lead it.").

D. The CFD Never Shows Squames Entering the Surgical Wound.

Plaintiffs also mischaracterized what Elghobashi's CFD actually shows. In their briefing, Plaintiffs claimed that Elghobashi's CFD would demonstrate that "the Bair Hugger transports particles to the surgical site." Dkt. No. 935, Pl. Summ. J. Opp. at 10. The Court relied on this claim in finding that Dr. Samet had adequate support for attributing the results of the Observational Study to airflow disruption by the Bair Hugger: "Recall that, Elghobashi simulates, using accepted physical principles, how the Bair Hugger could convect squames to the surgical wound." Dkt. No. 1024, Order at 8.

In fact, Elghobashi's CFD never shows a single squame landing in the surgical wound. Not one. And Elghobashi never claimed it did in either his report or trial testimony. Plaintiffs attempted to conceal this glaring defect at trial by speeding up the animation and making it more difficult to follow, but it was obvious to all observers when Defendants' counsel played the CFD at its original, as-produced-by-Elghobashi speed. In their closing,

Plaintiffs did not and could not dispute that the squames never enter the wound.[8] Trial Tr. at 2151:22-24. Plaintiffs also offered no rebuttal to the testimony of Defendants' airflow experts that the surgical wound creates its own plume of heat that provides a natural protective barrier. Trial Tr. (Keen) at 1585:8 to 1587:3; Trial Tr. (Abraham) at 1776:10-20 ("The patient is warmer than the room by quite a bit, and so the fact the patient is warm creates a plume of air, upward moving air by their skin and that upward movement of air protects the wound, and it sort of blocks any particulates from getting in.").

Dr. Abraham, Defendants' CFD expert, testified as follows after reviewing Elghobashi's CFD, played at the correct speed in front of the jury:

> Q. So that's the same video at the original speed?
>
> A. Yes.
>
> Q. Now, did you, the ladies and gentlemen were able to see it as we all looked along, but did you see a single particle actually go into the knee area?
>
> A. I did not.
>
> Q. And did you hear a lot of testimony it only takes one?
>
> A. I did.
>
> Q. Did you even see one?
>
> A. I did not.

[8] The National Institutes of Health prepared its own CFD and concluded: "there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection. . . . This investigation validates Moretti *et al.*'s conclusion that forced-air warming technology does not increase the risk of surgical wound infection." DX4, Memarzadeh at 1.

> Q. How does this relate to the concept of the thermo [sic – thermal] plume that you told us about and Dr. Memarzadeh spoke of?
>
> A. Well, Dr. Memarzadeh wrote about this protective effect of the thermo [sic – thermal] plume because the patient's body is warm and the knee is warm, and so that creates a uplift of air, air is actually rising next to the knee and that prohibits or blocks particles from getting in.
>
> Q. So the heat on the knee itself is protective?
>
> A. Yes.

Trial Tr. (Abraham) at 1779:23-16.

For all these reasons, Elghobashi's CFD does not fit the facts of the cases in this MDL. *See Daubert*, 509 U.S. at 591-92 ("'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes."). It admittedly does not reflect the conditions in a real world OR, does not show whether the Bair Hugger system meaningfully adds to turbulence in a real world OR, and does not show that the Bair Hugger system actually convects bacteria-bearing particles to the surgical wound. *See, e.g., Group Health, Inc.*, 344 F.3d at 761 (excluding expert where there was a "disconnect" between expert's testimony and plaintiffs' theory of the case). It therefore does not help the jury – indeed, it is likely only to confuse and mislead the jury, particularly when presented in the sped-up manner that Plaintiffs presented it in *Gareis.* Fed. R. Evid. 403. Accordingly, Elghobashi's testimony and CFD should be excluded.

E. The Other Studies Relied on by Plaintiffs' Experts Reach No Conclusions about the Bair Hugger's Effect in a Real-World Operation.

In addition to Elghobashi's CFD, Plaintiffs' medical experts cite several studies that they say support their airflow disruption theory. *E.g.*, Dkt. No. 1024, Order at 8 ("Samet

draws on Elghobashi's testimony, buttressed by scientific publications."). As the authors make clear, these studies suffer from the same problem as Elghobashi's CFD: they do not reflect real-world conditions. All were conducted in ORs or model ORs where other possible sources of air movement were minimized or eliminated entirely. The experimental conditions did not replicate anything close to a real-world joint surgery. None of Plaintiffs' medical experts ever opined in their reports or testified that these studies, standing alone without Elghobashi's CFD, provided sufficient support for their inference of general causation. Accordingly, if this Court concludes that the CFD does not provide a reliable foundation for the airflow-disruption theory, it must also conclude that these studies likewise do not independently provide a reliable foundation for the theory. *See Joiner*, 522 U.S. at 146.

McGovern 2011 (cited by Samet, Jarvis, and Stonnington). In addition to their Observational Study, the same researchers conducted a "bubble" experiment in an operating room in the UK. A mannequin was used in place of a human patient. A surgeon "stood motionless in front of the surgical site" and an anesthetist stood at the head of the operating table. DX1, McGovern at 1538. No other personnel were present, and there is no indication that any equipment other than the warming device was turned on. The researchers noted, however, that "even the slightest movement [of the surgeon or anaesthetist] adversely affected the natural airflow patterns over the surgical site." *Id.* at 1542. Furthermore, "[e]ven minor differences in factors such as draping, procedural practices and theatre dress are likely to have large effects on both floor-level and under-drape contaminant levels and the formation of convection currents." *Id.* at 1543. Due to

the limitations of the design and implementation of the experiment, the researchers were unable to reach a conclusion on whether the use of the Bair Hugger system increased bubbles over the surgical site as compared to a non-forced-air warming system.

Belani 2013 (cited by Samet, Jarvis, and Stonnington). This experiment was similar to McGovern's experiment with bubbles and a mannequin, but with one fewer (motionless) treater present. A single anesthesia provider "stood motionless at the head of the table behind the anesthesia/surgery draft." DX5, Belani at 2. There is no indication that any equipment other than the warming device was turned on, and the researchers note that the surgical lights were turned off. *Id.* at 5. The researchers cautioned that "the observed disruption [by the Bair Hugger system] was dependent on our exact setup (i.e., arrangement of draping, lights, and personnel), which did not include the presence of instrument trays and a working surgical team. Thus, we are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery." *Id.* at 5.

Legg 2012 (cited by Jarvis and Stonnington). In this study, the researchers set up an operating room with a volunteer "patient" and "single surgeon with no theatre nurse, assistant, or trays within the enclosure." DX6, Legg 2012 at 255. Wall extensions were placed around the operating table to "maximise the unidirectional airflow below the operative site." *Id.* No machinery other than the Bair Hugger was turned on, and no surgical personnel entered or left the room. Trial Tr. at 735:8-11 (Jarvis) ("Q. Okay. But no surgical personnel coming in or out? There's no machinery operating? There's no actual surgery going on, right? A. Correct."). The researchers were "unable to conclude that the use of the forced air device, which produced a change in temperature and increase in the

number of particles over the surgical site would actually lead to an increased risk of surgical site infection." DX6, Legg 2012 at 256. They cautioned that "[f]urther work is required to confirm that unidirectional airflow is disrupted by forced air patient warming devices *under our specific experimental theatre set-up* and future studies are needed to visualize the airflow over the surgical site." *Id.* (emphasis added).

Legg 2013 (cited by Samet, Jarvis, and Stonnington). The researchers placed a mannequin on a surgical table under unidirectional airflow in a "simulated" operating room. A single surgeon stood by the mannequin during the experiment. DX7, Legg 2013 at 407; Trial Tr. at 738:14-18 (Jarvis). 0.3 micron particles were measured; these were smaller than the particles tracked in Elghobashi's study. Trial Tr. at 739:14-15 (Jarvis). The researchers concluded: "This study does not show that forced-air warming increases the risk of infection – only that ***in certain types of theatre set-up*** it can significantly disrupt unidirectional airflow and draw particles from the potentially contaminated area below the sterile surgical field." *Id.* at 410 (emphasis added). The "certain type of theatre set-up" (one without a living patient, additional medical personnel, opening and closing of doors, and operating machinery) is not one that will be found anywhere in the real world.

Dasari 2012 (cited by Jarvis only). The researchers measured heat, not particles, in an "ultra-clean operating theatre" with purportedly laminar airflow. They noted the "limitation" that "the definitive effects of this excess heat on clinical outcomes are presently unknown." DX8, Dasari at 248. Though the researchers (unlike Legg) did incorporate some movement in the operating room, they conceded there would be more movement in a real operating room: "Although we attempted to mimic real conditions to

a certain extent by having two people walk around within the laminar flow area, ***in a working operating theatre there are more people and many other ways by which the [laminar flow] system might be disrupted***." *Id.* (emphasis added).

In sum, these studies, like Elghobashi's CFD, are too far removed from the conditions of real ORs and surgeries to support Plaintiffs' experts' conclusion that the Bair Hugger system causes PJIs in real-world operations. *See, e.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.").

III. A NEW STUDY BY THE SENIOR AUTHOR OF THE OBSERVATIONAL STUDY CONFIRMS THAT THE OBSERVATIONAL STUDY DOES NOT SUPPORT AN INFERENCE OF GENERAL CAUSATION.

This Court did not exclude the general causation testimony of Plaintiffs' medical experts because the association identified in the Observational Study was supported by the causation mechanism purportedly shown in Elghobashi's CFD. As Elghobashi's trial testimony confirms, his CFD does not show that the Bair Hugger causes PJIs in real-world OR conditions. For that reason alone, this Court should grant this motion. The new study co-authored by Dr. Mike Reed, senior author of the Observational Study, further confirms that the Observational Study cannot stand on its own to support an inference of general causation. *See Viagra*, 658 F. Supp. 2d at 944-45, 950 (D. Minn. 2009) (granting defendant's motion to exclude plaintiff's medical expert based on additional evidence

undermining epidemiological study on which the expert relied). This is a further, independent basis for excluding Plaintiffs' medical experts.

A. Plaintiffs' Medical Experts Cannot Infer Causation Without the Observational Study.

As the Court's general causation opinion recognizes, the Observational Study is essential to the opinions of Plaintiffs' medical experts; there is no general causation without it.[9] Indeed, the *Reference Manual on Scientific Evidence* rejects any attempt to infer causation merely from application of the Bradford-Hill criteria in the absence of epidemiological studies finding an association. *Id.* at 599 n.141 (3d ed. 2011) ("There may be some logic to that effort, but it does not reflect accepted epidemiologic methodology."). While there may be some types of cases where epidemiological evidence is not required to prove general causation, cases like this (where there are many possible known causes of the relevant medical injury) are not among them. *See, e.g.*, *In re Bausch & Lomb Inc.*, MDL No. 1785, 2009 WL 2750462, *12 (D.S.C. Aug. 26, 2009) (concluding that "tests' suggestion of biological plausibility is insufficient to demonstrate causation and unreliable under *Daubert*, absent evidence establishing an association between [the defendant's product] and non-Fusarium infections."); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 498-99 (E.D. Pa. 2016) ("Without admissible expert testimony based on the epidemiological evidence, Plaintiffs instead have cobbled together

[9] *E.g.*, DX9, Samet Dep. at 282:16-23 ("The McGovern paper supplies the only estimate of the risk associated for deep joint infection associated with use of the forced-air warming Bair Hugger device. So absent the quantitative estimate from that paper, it would be – while there would be a quite plausible mechanistic basis for increased risk, there would not been asked [sic] an association in – in the real world.").

evidence of biological plausibility, specific causation opinions based on an assumption that general causation has been established, and anecdotal evidence. Taken together, Plaintiffs' potentially admissible evidence supports no more than an association between Zoloft and certain birth defects . . .. Causation must be based upon more than a possibility.").

For this reason, much of Defendants' original *Daubert* briefing was devoted to the observational component of the McGovern study (termed the "Observational Study" in the Court's general causation order) and the reasons it lacked sufficient indicia of reliability. As Defendants explained, the results of the Observational Study were likely confounded by many factors (some of which were expressly noted by the researchers), including (i) changes in anti-clotting and antibiotic drug regimens and (ii) the hospital's introduction of several infection-reducing measures late in the Bair Hugger period of the study or during the non-Bair-Hugger period.[10]

B. The Jeans Study Confirms that the Observational Study Was Confounded by Introducing MSSA Screening.

Among these defects, Defendants noted that introduction of MSSA screening near the end of the Bair Hugger-only period, and its use throughout the HotDog period, likely had a statistically significant impact on infection rates in favor of the HotDog cohort. Dkt. No. 913, Def. Opp. to Mot. to Exclude at 34-35 ("Because MSSA screening was not

[10] Defendant's biostatistics expert, Dr. Holford, also concluded that the study data was mistabulated and raised additional concerns about the statistical analysis (which was performed by a longtime employee of Dr. Scott Augustine). Dkt. 926-1, Holford Rpt. at 2-3, 5. *See Viagra*, 658 F. Supp. 2d at 945 ("Peer review and publication mean little if a study is not based on accurate underlying data."); *see also Joiner*, 522 U.S. at 146 (where expert opinion was founded on statistically insignificant data and other doubtful evidence, district court did not abuse discretion by excluding the opinion).

implemented until January 2010, most Bair Hugger patients in the McGovern study would not have had the benefit of MSSA screening. Most Bair Hugger patients had their surgery conducted at a time when the MSSA infection rates were themselves nearly one percent."). Plaintiffs and their experts responded that no published study had demonstrated that MSSA screening had a significant impact. DX15, 10/25/17 Hrg. Tr. at 242:15-18 (MR. SACCHET: "The MSSA nasal screening is in the nose. It can perhaps cleanse bacteria, but the biological plausibility is questionable, and in light of that, I don't think the authors have taken the step to conduct a true study to show that it is not a confounder, but it's the opposite burden.").

That study now exists, and proves Defendants were correct. In July 2018, Dr. Mike Reed (senior author of the Observational Study) and his colleagues published a study specifically addressing the impact of MSSA screening. DX10, Jeans, *et al*. "MSSA screening and decolonisation in elective hip and knee arthroplasty." *J. Infection* (2018) (the "Jeans study"). The Jeans study included the same time period and patients as the Observational Study. DX11, Borak *Axline* Rpt. ¶ 21.

Using a multivariate analysis,[11] the Jeans study demonstrated that the MSSA screening and decolonization reduced *staph aureus* infections by two-thirds, and the

[11] Unlike the Observational Study, which used only univariate analysis. Defendants' epidemiology expert, Dr. Borak, addressed the importance of multivariate analysis in his expert report in *Axline*: "An important limitation of the McGovern study was that its analyses were only univariate, thus the effects of confounders were ignored. The Jeans study employed multivariate analysis, indicating that Reed and colleagues recognized the greater statistical meaningfulness of studies that simultaneously consider the impacts of confounding factors." DX11, Borak *Axline* Rpt. ¶ 21b.

overall infection rate also went down by a statistically significant amount. While noting that "improvement in infection rates could have been down [sic] to other factors . . .," the authors conclude that the "dramatic reduction in MSSA SSI [surgical site infections] . . . suggest that screening and decolonization was responsible." DX10, Jeans at 4. In other words, the Jeans study confirms Defendants' contention that the introduction of MSSA screening was a confounding factor and helps explain the reduction in PJIs reported during the non-Bair Hugger period of the Observational Study. DX11, Borak *Axline* Rpt. ¶ 21 ("This study confirms that adoption of MSSA screening almost exclusively for patients using the non-[Bair Hugger] warmer confounded the results of the McGovern study.").

So why does this change the equation? It is true that the Court characterized the confounding factors identified by Defendants as "alternative explanations for the observed hospital's drop-off in infections," and noted that Plaintiffs' experts were not required to rule out all alternative explanations. Dkt. No. 9, Order at 9 (*citing Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 563 (8th Cir. 2014)). But while an expert need not *rule out* all possible causes of an injury, there is a point where an epidemiological study is too flawed to be a reliable foundation for *ruling in* a cause. *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230 (W.D. Wash. 2003) ("When faced with epidemiological evidence, the court must determine whether the flaws compromise the study's findings."). That is particularly so where, as here, Plaintiffs rely on a single epidemiological study to support their inference of general causation. As stated in the *Reference Manual*, observational studies provide "good evidence" of causation only when (i) the same association is seen in other studies with different designs and subjects and

(ii) the association holds when confounders are taken into account by appropriate methods. *Id.* at 221. Neither is true here. The association found in the Observational Study has not been replicated in any other epidemiological study,[12] and the researchers expressly did not account for the effects of confounders. The researchers also disclaimed any finding of causation. *See In re Mirena IUS Levonorgestrel-related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 251-52 (S.D.N.Y. 2018) (excluding medical causation expert who relied on a single retrospective observational study that did not find causation and did not control for "major confounding variables").

Considering the findings of the Jeans study alongside the other disclosed and undisclosed confounders (not to mention evidence of data manipulation), the Court should now reconsider its order and conclude that the flaws of the Observational Study render it an unreliable foundation for Plaintiffs' experts to infer general causation, either alone or when considered with Plaintiffs' other sources. As the *Reference Manual* makes clear, qualified experts may not infer general causation from a single observational study that fails to account for established confounders. The opinions of Plaintiffs' medical experts are "so fundamentally unsupported that [they] can offer no assistance to the jury," and should therefore be excluded. *Children's Broad.*, 357 F.3d at 864.

[12] Except the debunked study published by Scott Augustine in 2017 and repudiated by Plaintiffs' medical experts after Augustine's scientific fraud was exposed. Dkt. No. 955, Def. Med. Experts Reply at 42-48.

IV. THE NEW INTERNATIONAL CONSENSUS REINFORCES THAT PLAINTIFFS' EXPERTS HAVE MADE AN IMPROPER INFERENCE.

The International Consensus Meeting on Prevention of Musculoskeletal Infection (ICM) agrees, overwhelmingly, that such an inference of general causation cannot be made. After considering the Observational Study, Elghobashi's published article on his CFD, and the other articles cited by Plaintiffs, the delegates to the 2018 ICM voted by a 93% to 2% margin (per the 2018 ICM) to support the conclusion that "There is no evidence to definitively link FAW to an increased risk of SSIs/PJIs." The ICM's statement of rationale (of which Dr. Reed himself, the senior author of the Observational Study, is a listed co-author) discusses the Observational Study and its confounders in detail.[13] It also considers the Observational Study alongside Elghobashi's CFD and the other papers cited by Plaintiffs. The statement nonetheless concludes there was a "lack of strong evidence linking FAW to increased risk of SSI." DX2, 2018 ICM at 113.

The ICM met in July 2018 and published the report of its consensus statements online on November 12, 2018.[14] The ICM's statements were "compiled as the result of work of over 800 individuals from around the globe," including delegates from all

[13] As the ICM's statement of rationale notes, "studies of the same cohorts by these researchers [the McGovern researchers] revealed potential impacts unrelated to the change in warming modality, including thromboprophylaxis [citing Jensen] and methicillin-sensitive Staphylococcus aureus screening [citing Jeans]." DX2, 2018 ICM at 112. As discussed in Defendants' *Daubert* briefing, the Jensen study confirmed that the use of rivaroxaban, an anti-clotting drug, during the Bair Hugger-only period, could explain the difference in infection rates. DX12, Jensen; Dkt. No. 913, Def. Opp. at 16-19.

[14] The new ICM statements were not available when Defendants filed their letter requesting leave to seek reconsideration on August 14, 2018. Dkt. No. 1428. Accordingly, they were not referenced in the letter.

subspecialties of orthopedics. Of particular significance to this litigation, the delegates considered the same scientific studies upon which Plaintiffs relied in their Master Complaint and at the *Gareis* trial and concluded: "There is no evidence to definitely link FAW [forced air warming] to an increased risk of SSIs/PJIs [surgical site infections/periprosthetic joint infections]." The delegates reached what the ICM terms a "strong consensus." Ninety-three percent of the participating delegates voted in support of the consensus statement, while only 2 percent voted against. The supporting statement of the ICM's rationale concludes:

- "Maintaining intraoperative normothermia has been shown to reduce perioperative complications including SSI. FAW represents one of the most widely-used methods to prevent hypothermia and maintain intraoperative normothermia."

- "In conclusion, the literature is conflicting and there is still a lack of strong evidence linking FAW to increased risk of SSI. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time."

DX2, 2018 ICM at 112-14. The rationale expressly addresses the same sources relied upon by Plaintiffs' medical experts to support their inference of general causation: the Observational Study, Belani, Legg 2012, Legg 2013, Dasari, and the published version of Elghobashi's CFD (He, et al. 2018). *Id.* n.1, 4, 5, 6, 7, 8.

The ICM delegates also reached a "strongest consensus" (97 percent agree, 1 percent disagree) recommending that normothermia be maintained in patients undergoing orthopedic procedures. *Id.* at 115. The supporting statement concluded: "There are no studies which provide high-level evidence that warming systems may increase infection

rates." *Id.* at 116. This statement expressly considered and referenced McGovern 2011 and Legg 2013. *Id.* n.14, 15.

While an expert's inference of causation need not be generally accepted to be admissible, "'general acceptance' can yet have a bearing on the inquiry." *Daubert*, 509 U.S. 579, 594 (1993). "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community,' *Downing*, 753 F.2d at 1238, may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594; *see also Olson v. Ford Mot. Co.*, 481 F.3d 619 (8th Cir. 2007) (general acceptance is "one of multiple factors that a district court must consider in deciding whether to admit expert evidence under Rule 702").

The new ICM statements confirm that the technique of Plaintiffs' medical experts – inferring from Elghobashi's CFD and various experimental studies that the Bair Hugger system causes PJIs by disrupting the patient-protecting "forcefield" – "has been able to attract only minimal support within the community." The ICM's conclusions echo the prior conclusions of AORN, ECRI, the Duke Infection Control Outreach Network, the FDA, and others. *See* Dkt No. 762, Def. Summ. J. Mem. at 17-19.

In sum, the overwhelming consensus of experts in the field who have reviewed the science is that no causation inference can be made based on the scientific evidence. In opining that the Bair Hugger system causes PJIs (an opinion they reached for the first time in this litigation), Plaintiffs' experts stretch beyond what the science can support.[15] *See*

[15] The theoretical (and unlikely) possibility that future research could provide a more

Joiner, 522 U.S. at 146; *Mirena IUD*, 169 F. Supp. 3d at 429-30 (excluding general causation expert's theory of causation, which was developed for the litigation and had not achieved general acceptance within the scientific community).

V. IN THE ALTERNATIVE, THE COURT SHOULD CERTIFY THE GENERAL CAUSATION ISSUE UNDER SECTION 1292(B).

If the Court concludes that Plaintiffs' medical experts remain admissible under Eighth Circuit law, Defendants request that the Court certify its order for immediate interlocutory appeal under 28 U.S.C. § 1292(b). The criteria for Section 1292(b) certification are readily satisfied.

First, admissibility of Plaintiffs' medical causation experts turns on the controlling legal question of whether the standard is reliance on "scientifically valid evidence," *Glastetter v. Novartis Pharms. Corp*., 252 F.3d 986 (8th Cir. 2001), or the more permissive "fundamentally unsupported" standard cited in the Court's Order. ECF No. 1024 at 3 (*quoting Children's Broad.*, 357 F.3d at 864).[16] The more permissive language is unique to a strand of Eighth Circuit case law and originates in pre-*Daubert* decisions. The original version appears in *Loudermill v. Dow Chemical Co*., 863 F.2d 566, 570 (8th Cir. 1988), where the Court held that "if an expert opinion is so fundamentally unsupported that it can offer no assistance to the jury, then the testimony should not be admitted." In *Hose v.*

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reliable foundation for Plaintiffs' experts does not make their opinions admissible. *See Mirena IUD*, 169 F. Supp. 3d at 450 ("[I]t is not that experts 'are insincere in their opinions or that their opinions may not some day be validated through scientific research and experiment; it is simply that the law cannot wait for such a confirmation.").

[16] Defendants contend, of course, that Plaintiffs' experts are not admissible under either standard.

Chicago N.W. Transp. Co., 70 F.3d 968, 974 (8th Cir. 1995), the panel rephrased this into an even more permissive rule: "Only if an expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded" (internal quotation omitted). The *Hose* language was echoed in *Children's Broad. Corp.* It has never appeared in the case law of any other U.S. Court of Appeals.

Second, there is substantial ground for difference of opinion, as the conflicting Eighth Circuit admissibility standards show.

Third, certification would materially advance the termination of the litigation. For all the reasons argued in Defendants' original general causation briefing and this memorandum, Plaintiffs' medical experts' opinions are plainly inadmissible under the *Glastetter* standard. If the Eighth Circuit agrees that *Glastetter* controls, Plaintiffs' experts' opinions must be excluded and summary judgment granted on all cases in the MDL. *See, e.g.*, *In re Blue Cross Blue Shield Antitrust Litig.*, MDL No. 2406, 2018 WL 3326850, *6 (N.D. Ala. June 12, 2018) ("Given the nationwide scope and importance of this multidistrict litigation, the need for § 1292(b) review is particularly compelling.").

Finally, now is the perfect time to certify the general causation issue. The *Gareis* appeal is pending before the Eighth Circuit. In their Notice of Cross-Appeal, Defendants identified the inadmissibility of Plaintiffs' general causation experts as an alternative basis to affirm the *Gareis* judgment. *Gareis*, Dkt. No. 525. It would greatly benefit the MDL for the Eighth Circuit to address all these issues, including general causation, at the same time.

CONCLUSION

For all the foregoing reasons, this Court should reconsider its December 2017 order, exclude Plaintiffs' medical experts and Dr. Elghobashi and his CFD pursuant to Fed. R. Evid. 702, and grant summary judgment on general causation in favor of Defendants. In the alternative, the Court should certify the general causation issue to the Eighth Circuit pursuant to Section 1292(b).

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Respectfully submitted,

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